REMARKS

Previous claims 14-49 are withdrawn and new claims 50-95 presented above.

Re: Rejection under 32 U.S.C. 112.

In items 1 and 2 of the office action, claims 14-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. New claims 50-95 are derived from cancelled claims 14-49 which are now amended to particularly point out and distinctly claim that which the applicants consider to be their invention. In the new claims 50-95, there are two independent claims, wherein new claim 50 is derived from former claim 14, and new claim 73 is derived from former claim 15. New dependent claims 51 to 72 and 94 each depend on new claim 50; new dependent claims 74 to 93 and 95 each depend on new claim 73. A marked up version of claims 50 to 95 is attached to assist in showing amendments made to claims 14-19.

In item 2 of the current office action, the Examiner has objected to the inclusion of additional ingredients in dependent claims after the amendment in the claim 1 that changed "comprising" to "consisting essentially of." In new independent claims 50 and 73, the applicants revert to the use of the term "comprising" in view of the clarifying changes made to the remainder of these claims. The independent claims now recite all components of the process to prepare the rapidly disintegrating solid dosage form of the invention, and no additional ingredients are claimed in the dependent claims. In addition, specific compounds are claimed in dependent claims as specific matrix-forming agents and surface modifiers.

Recitation of the terms "inorganic additives," "inorganic material" and "colloidal clay" have been removed from the claims.

Cellulose materials can function as surface modifiers, and specific charged compounds sodium carboxymethylcellulose and calcium carboxymethylcellulose have been claimed in claims 66 and 89. Cellulose materials can also function as matrix-forming agents, and are claimed as such in claims 51, 53, 74, and 76.

Recitation of the terms "natural polymers" and "synthetic polymers" have been removed from the claims. The term "polysaccharide" is recited in claims 51 and 74 without distinction between natural polysaccharide and synthetic polysaccharide.

Recitation of the term "tribasic calcium phosphate" has been removed from the claims. The term "pH buffering salt" is recited in claims 51, 52, 53, 74, 75, and 76.

Recitation of both of the terms "synthetic phospholipid" and the unclear term "semisynthetic phospholipid" have been removed from the claims.

Recitation of the unclear term "desalted" has been removed from the claims.

Recitation of the improper trade names "Phospholipon 100H, Lipoid E80" have been removed from the claims.

The Examiner is unclear how cholesterol can function as a surfactant. In the context of the invention, cholesterol comprises a hydrophilic alcohol hydroxyl functional group attached to a hydrocarbon steroid ring system which is further substituted with an aliphatic hydrocarbon chain. The combination of hydrophilic and hydrophobic groups in the same molecule and the compatibility of cholesterol with phospholipids permits this molecule to serve as a second service modifier. Cholesterol is a relatively hydrophobic second surface modifier. However, recitation of "cholesterol" as a second surface modifier has been removed from the claims.

The Examiner is unclear how various celluloses can have surfactant properties. In the new claims, only specific charged compounds sodium carboxymethylcellulose and calcium carboxymethylcellulose have been claimed in claims 66 and 89. These materials comprise a hydrophilic anionic carboxylate together with hydroxyl functional groups as, for example, alcohol and hemiketal-like groups. These materials also comprise oxycarbocyclic rings with C-H bonds, which are hydrophobic groups. The combination of the highly hydrophilic anionic carboxylates and the less hydrophilic/more hydrophobic oxycarbocyclic rings and C-H bonds in the same molecule permits the charged carboxymethylcellulose to serve as surface modifiers.

Recitation of the unclear term "enteric resin" has been removed from the claims.

Recitation of the term "lyophilization" has been removed from the claims, removing the lack of clarity issue.

The term "antisolvent" is a commonly known in the art, particularly with respect to supercritical fluid technology. The Examiner will recall in this respect that if one creates a solution of a drug in a first solvent, the drug may be precipitated from the first solvent by addition of an antisolvent. In this regard, an antisolvent is a second solvent that can dissolve the first solvent but which cannot simultaneously dissolve the drug.

Applicants submit the claims as above presented find basis in the original disclosure and are compliant with 35 U.S.C. §112, second paragraph

Re: Rejections under 35 U.S. C. 102 and 103

In items 3 and 4 of the office action, claims 14-17, 19-34 and 35-49 are rejected as being anticipated by and unpatentable over Green, U.S. 5,976,577. However, the process of Green requires an increase in the viscosity of a suspension of uncoated or coated coarse

particles of a pharmaceutically active substance to keep the coarse particles of Green from settling. This is accomplished by adding a carrier material to the coarse particle suspension of Green and by performing a cooling step to increase viscosity. The suspension of coarse particles of Green is inherently unstable, and the coarse particles of Green which may be coated or uncoated otherwise do not remain suspended. Unlike the teachings of Green, in the process of the current invention as now claimed, the primary particles of the current process are much smaller (0.05 to 10 micrometers) than the coarse particles of the process of Green (50 to 400 micrometers). The primary particles of the current invention exist as a **stable suspension** and do not require a viscosity-increasing step to maintain the suspension. Each of the particles of the current invention is a solid drug particle on to which is adsorbed at least one surface modifying agent of which one is a phospholipid. The admixture of the stable aqueous homogeneous suspension of micronized surface stabilized primary particles of a water-insoluble or poorly water-soluble drug with a matrix-forming bulking/releasing agent or a mixture of matrix-forming bulking and releasing agents is dried to a solidified suspension of said surface stabilized primary particles dispersed and embedded throughout a support matrix of said matrix-forming agent or agents. The matrix formed in the process of the current invention dissolves or substantially disperses in a rapid disintegration time when in contact with an aqueous environment to release the surface stabilized primary particles into the aqueous environment as a suspension without irreversible particle aggregation and/or particle agglomeration and without particle size growth. This is not taught by Green, nor is the formation of a solidified suspension of primary particles. Further, Green teaches away from small particles in his invention; see Green, column 3, lines 6 to 18:

> "Size of the particles has an important effect on the rate of release of drug when coated. A smaller particle has a much larger overall surface area for diffusion. As a result, the rate of release of drug is greater the smaller the particle. Current coating techniques are able to effectively coat particles greater than 100 .mu.m, whereas particles less than 100 .mu.m may not have an intact coat, which will

result in rapid release of the drug once in suspension. Coating of larger particles therefore decreases the rate of release of drug. Typically, according to the present invention, the coarse particles may have a size of up to 1 millimeter, although the average size is generally up to about 500 .mu.m, for example 75 to 400 .mu.m, more usually in the region of about 100-300 .mu.m."

Re: rejection under 35 U.S.C. 103(a) as being unpatentable over Green in view of Libby (US 4,432,975), the use of polyethylene glycol is no longer claimed in the current invention.

Re: rejection under 35 U.S.C. 103(a) as being unpatentable over Green in view of Carli (US 5,164,380)), the use of colloidal silica is no longer claimed in the current invention.

The claims of the current invention now recite the critical steps of:

forming an admixture of a **stable aqueous homogeneous suspension** of micronized surface stabilized primary particles of a water-insoluble or poorly water-soluble drug with a matrix-forming bulking/releasing agent or a mixture of matrix-forming bulking and releasing agents; and

drying said admixture to a solidified suspension of said surface stabilized primary particles dispersed and embedded throughout a support matrix of said matrix-forming agent or agents. These critical steps that lead to the distinct particles and dosage forms of the current invention are not taught by Green. Reconsideration of the declaration filed by the applicants in view of the new claims is respectfully requested.

For the above reasons it is respectfully submitted the claims of this application define patentable subject matter. Reconsideration and allowance are solicited.

Attached hereto is a marked-up version of claims 50-95 to show changes.

amendment. The attached page(s) is captioned "**Version With Markings To Show Changes Made**."

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

Marked up version of claims 50-95 to show changes

50. (New, derived from claim 14) A process for the preparation of a rapidly disintegrating solid dosage form comprising the steps of:

a) forming an admixture of a stable (see page 3, line 27) aqueous homogeneous suspension of micronized surface stabilized (see former claim 1) primary particles of a water-insoluble or poorly water-soluble drug with a matrix-forming bulking/releasing agent or a mixture of matrix-forming bulking and releasing agents, wherein said stable aqueous primary particle suspension has dispersity with volume weighted mean particle size from 0.2 micrometers to 5 micrometers, each primary particle is a solid (see page 4, line 10) drug (see page 1, line 5) particle on to which is adsorbed at least one surface modifying agent of which one is a phospholipid (see page 4, line 10-12), said matrix-forming agent or agents are present in an amount sufficient to allow drying of said admixture to a solidified suspension (see page 8, line 15) without irreversible particle aggregation and/or particle agglomeration or particle growth (see page 4, line 25-26); then,

b) drying said admixture to a solidified suspension (see page 8, line 15) of said surface stabilized primary particles dispersed and embedded (see page 7, line 6) throughout a support matrix of said matrix-forming agent or agents, wherein said matrix dissolves or substantially disperses in a rapid disintegration time when in contact (see page 7, line 7) with an aqueous environment to release said surface stabilized primary particles into said aqueous environment as a suspension (see page 9, line 5) without irreversible particle aggregation and/or particle agglomeration and without particle size growth; then,

c) optionally coarse milling and blending said solidified suspension with one or more pharmaceutically acceptable excipients to provide a dried powder; and then,

d) forming said dried material or said dried powder into a solid dosage form.

51. (New from claim 16 and 20) The process of claim [15 or 16] 50, wherein the matrix-forming bulking/releasing agent is selected from the group consisting of a pharmaceutically acceptable saccharide[s], a pharmaceutically acceptable polysaccharide[s], a pharmaceutically acceptable humectant[s], [natural polymers, synthetic polymers, inorganic additives, and] a pharmaceutically acceptable cellulose based polymer[s], combinations thereof, and combinations of these with a pH buffering salt (see claim 20).

52. (New, derived from claim 17 and 20) The process of claim [16] 50, wherein the [saccharide or polysaccharide] matrix-forming bulking/releasing agent is selected from the group consisting of mannitol; trehalose; [lactose, sucrose,] sorbitol; maltose; [and] combinations thereof; combinations of mannitol, trehalose, sorbitol, and maltose with lactose (see claim 16 in view of page 12, line 12); combinations of mannitol, trehalose, sorbitol, maltose, and lactose with sucrose (see page 12, line 20); and combinations thereof with a pH buffering salt (see claim 20).

53. (New from claim 17, 20, and 21) The process of claim [16] 50, wherein the matrix-forming bulking/releasing agent [cellulose based polymer] is selected from the group consisting of mannitol; trehalose; sorbitol; maltose; combinations of mannitol, trehalose, sorbitol, and maltose with lactose (see claim 16 in view of page 12, line 12); combinations of mannitol, trehalose, sorbitol, maltose, and lactose with sucrose (see page 12, line 20); microcrystalline cellulose; hydroxymethyl cellulose; hydroxypropyl cellulose; methylcellulose; [and] combinations thereof, and combinations thereof with a pH buffering salt (see claim 20).

54. (New from claim 42) The process of claim [14 or 15] 50, wherein the [amount of] matrix-forming agent is present in an amount between 0.1% w/w and 90% w/w.

55. (New from claim 22) The process of claim [14 or 15] 50, wherein the rapid disintegration time is less than 2 minutes.

56. (New from claim 24) The process of claim [14 or 15] 50, wherein the drug is selected from the group consisting of antifungal agents, immunosuppressive agents, immunoactive agents, antiviral agents, antineoplastic agents, analgesic agents, antiinflammatory agents, antibiotic agents, antiepileptic agents, anesthetic agents, hypnotic agents, sedative agents, antipsychotic agents, neuroleptic agents, antidepressant agents, anxiolytic agents, anticonvulsant agents, antagonist agents, neuron blocking agents, anticholinergic agents, cholinomimetic agents, antimuscarinic agents, muscarinic agents, antiadrenergic agents, antarrhythmic agents, antihypertensive agents, hormones, and nutrients.

57. (New from claim 25) The process of claim [14 or 15] 50, wherein the drug is selected from the group consisting of fenofibrate, itraconazole, [or] and cyclosporine.

58. (New from claim 43) The process of claim [14 or 15] 50, wherein the drug is present in an amount between 0.1% w/w and 60% w/w.

59. (New from claim 27) The process of claim [26] 50, wherein the [natural] phospholipid is selected from the group consisting of an egg phospholipid, a soybean phospholipid, [or a] and combinations thereof.

60. (New from claim 28) The process of claim [26] 50, wherein the phospholipid is [salted, desalted,] selected from the group consisting of hydrogenated phospholipid, [or] partially hydrogenated phospholipid, and combinations thereof.

61. (New from claim 29) The process of claim [26] 50, wherein the phospholipid is selected from the group consisting of [Phospholipon 100H, Lipoid E80,] phosphatidylcholine, phosphatidylethanolamine, phosphatidylserine, phosphatidylinoistol, phosphatidylglycerol, phosphatidic acid, a lysophospholipid, and combinations thereof.

62. (New from claim 30) The process of claim [14 or 15] 50, wherein the surface modifier is selected from the group consisting of pharmaceutically acceptable [natural surfactants,] pharmaceutically acceptable nonionic surfactants, pharmaceutically acceptable anionic surfactants, and pharmaceutically acceptable cationic surfactants[, and colloidal clays].

63. (New from claim 31) The process of claim [30] 50, wherein the surface modifier is selected from the group consisting of [pharmaceutically acceptable natural surfactant is] casein, gelatin, tragacanth, [a wax, an enteric resin, paraffin,] acacia, [cholesterol, or a] and combinations thereof.

64. (New from claim 32 as first part with next claim) The process of claim [30] 50, wherein the [nonionic surfactant is] surface modifier is selected from the group consisting of a pharmaceutically acceptable polyoxyethylene fatty alcohol ether, a sorbitan fatty acid ester, a polyoxyethylene fatty acid ester, [a sorbitan ester, glycerol monostearate, a polyethylene glycol, cetyl alcohol, cetostearyl alcohol, stearyl alcohol,] a poloxamer, a polaxamine, [methylcellulose, hydroxycellulose, hydroxypropylcellulose, hydroxypropylmethylcellulose, noncrystalline cellulose, or a] and combinations thereof.

65. (New from claim 32 as second part with previous claim) The process of claim [30] 50, wherein the [nonionic surfactant is] surface modifier is selected from the group consisting of [a pharmaceutically acceptable polyoxyethylene fatty alcohol ether, a

sorbitan fatty acid ester, a polyoxyethylene fatty acid ester, a sorbitan ester,] glycerol monostearate, [a polyethylene glycol,] cetyl alcohol, cetostearyl alcohol, stearyl alcohol, [a poloxamer, a polaxamine, methylcellulose, hydroxycellulose, hydroxypropylcellulose, hydroxypropylmethylcellulose, noncrystalline cellulose, or a] and combinations thereof.

66. (New from claim 33) The process of claim [30] 50, wherein the [anionic surfactant] surface modifier is selected from the group consisting of potassium laurate, triethanolamine stearate, sodium lauryl sulfate, an alkyl polyoxyethylene sulfate, sodium alginate, sodium deoxycholate, dioctyl sodium sulfosuccinate, a negatively charged glyceryl ester[s], sodium carboxymethylcellulose, calcium carboxymethylcellulose, [or a] and combinations thereof.

67. (New from claim 34) The process of claim [30] 50, wherein the [cationic surfactant] surface modifier is [a pharmaceutically acceptable quaternary ammonium compound] selected from the group consisting of benzalkonium chloride, cetyltrimethylammonium bromide, lauryldimethylbenzylammonium chloride, and [a] combinations thereof.

68. (New from claim 41) The process of claim [14 or 15] 50, wherein the surface modifier is present in an amount between 0.5% w/w and 50% w/w.

69. (New from claim 36) The process of claim [14] 50, wherein the admixture is dried by spray drying, spray coating, or freeze-drying.

70. (New from a combination of claim 37 and 38) The process of claim [38] 50, wherein the micronized primary particles are prepared in a particle fragmentation process [is] selected from the group consisting of sonication, milling, homogenization, microfluidization, [or] and antisolvent and solvent precipitation.

71. (New from claim 39) The process of claim [14] 50, wherein the pharmaceutically acceptable excipient is a tableting aid for compression, a glidant for hard gelatin encapsulation, an effervescent disintegration agent, a dispersant for a dry powder inhaler, or a combination thereof.

72. (New from claim 40) The process of claim [14 or 15] 50, wherein the dosage form is a tablet, a gelatin encapsulation, or a powder.

73. (New, derived from claim 15) A process for the preparation of a rapidly disintegrating solid dosage form comprising the steps of:

a) forming an admixture of a stable (see page 3, line 27) aqueous homogeneous suspension of micronized surface stabilized (see former claim 1) primary particles of a water-insoluble or poorly water-soluble drug with a matrix-forming bulking/releasing agent or a mixture of matrix-forming bulking and releasing agents, wherein said stable aqueous primary particle suspension has dispersity with volume weighted mean particle size from 0.2 micrometers to 5 micrometers, each primary particle is a solid (see page 4, line 10) drug (see page 1, line 5) particle on to which is adsorbed at least one surface modifying agent of which one is a phospholipid (see page 4, line 10-12), said matrix-forming agent or agents present in an amount sufficient to allow drying of said admixture to a solidified suspension (see page 8, line 15) without irreversible particle aggregation and/or particle agglomeration or particle growth (see page 4, line 25-26); then,

b) distributing the admixture of step (a) into unit dosage form molds; and then,

c) freeze-drying said admixture in said unit dosage form molds to a solidified suspension (see page 8, line 15) of said surface stabilized primary particles dispersed and embedded (see page 7, line 6) throughout a support matrix of said matrix-forming agent or agents, wherein said matrix dissolves or

substantially disperses in a rapid disintegration time when in contact (see page 7, line 7) with an aqueous environment to release said surface stabilized primary particles into said aqueous environment as a suspension (see page 9, line 5) without irreversible particle aggregation and/or particle agglomeration and without particle size growth.

74. (New from claim 16) The process of claim [15 or 16] 73, wherein the matrix-forming bulking/releasing agent is selected from the group consisting of a pharmaceutically acceptable saccharide[s], a pharmaceutically acceptable polysaccharide[s], a pharmaceutically acceptable humectant[s, natural polymers, synthetic polymers, inorganic additives, and] a pharmaceutically acceptable cellulose based polymer[s], combinations thereof, and combinations of these with a pH buffering salt (see claim 20).

75. (New, derived from claim 17) The process of claim [16] 73, wherein the [saccharide or polysaccharide] matrix-forming bulking/releasing agent is selected from the group consisting of mannitol; trehalose; [lactose, sucrose,] sorbitol; maltose; [and] combinations thereof; combinations of mannitol, trehalose, sorbitol, and maltose with lactose (see claim 16 in view of page 12, line 12); combinations of mannitol, trehalose, sorbitol, maltose, and lactose with sucrose (see page 12, line 20); and combinations thereof with a pH buffering salt (see claim 20).

76. (New from claim 17, 20, and 21) The process of claim [16] 73, wherein the matrix-forming bulking/releasing agent [cellulose based polymer] is selected from the group consisting of mannitol; trehalose; sorbitol; maltose; combinations of mannitol, trehalose, sorbitol, and maltose with lactose (see claim 16 in view of page 12, line 12); combinations of mannitol, trehalose, sorbitol, maltose, and lactose with sucrose (see page 12, line 20); microcrystalline cellulose; hydroxymethyl cellulose;

hydroxypropyl cellulose; methylcellulose; [and] combinations thereof, and combinations thereof with a pH buffering salt (see claim 20).

77. (New from claim 42) The process of claim [14 or 15] 73, wherein the [amount of] matrix-forming agent is present in an amount between 0.1% w/w and 90% w/w.

78. (New from claim 22) The process of claim [14 or 15] 73, wherein the rapid disintegration time is less than 2 minutes.

79. (New from claim 24) The process of claim [14 or 15] 73, wherein the drug is selected from the group consisting of antifungal agents, immunosuppressive agents, immunoactive agents, antiviral agents, antineoplastic agents, analgesic agents, antiinflammatory agents, antibiotic agents, antiepileptic agents, anesthetic agents, hypnotic agents, sedative agents, antipsychotic agents, neuroleptic agents, antidepressant agents, anxiolytic agents, anticonvulsant agents, antagonist agents, neuron blocking agents, anticholinergic agents, cholinomimetic agents, antimuscarinic agents, muscarinic agents, antiadrenergic agents, antarrhythmic agents, antihypertensive agents, hormones, and nutrients.

80. (New from claim 25) The process of claim [14 or 15] 73, wherein the drug is fenofibrate, itraconazole, or cyclosporine.

81. (New from claim 43) The process of claim [14 or 15] 73, wherein the drug is present in an amount between 0.1% w/w and 60% w/w.

82. (New from claim 27) The process of claim [26] 73, wherein the [natural] phospholipid is selected from the group consisting of an egg phospholipid, a soybean phospholipid, [or a] and combinations thereof.

83. (New from claim 28) The process of claim [26] 73, wherein the phospholipid is [salted, desalted,] selected from the group consisting of hydrogenated phospholipid, [or] partially hydrogenated phospholipid, and combinations thereof.

84. (New from claim 29) The process of claim [26] 73, wherein the phospholipid is selected from the group consisting of [Phospholipon 100H, Lipoid E80,] phosphatidylcholine, phosphatidylethanolamine, phosphatidylserine, phosphatidylinoistol, phosphatidylglycerol, phosphatidic acid, a lysophospholipid, and combinations thereof.

85. (New from claim 30) The process of claim [14 or 15] 73, wherein the surface modifier is selected from the group consisting of pharmaceutically acceptable [natural surfactants,] pharmaceutically acceptable nonionic surfactants, pharmaceutically acceptable anionic surfactants, and pharmaceutically acceptable cationic surfactants[, and colloidal clays].

86. (New from claim 31) The process of claim [30] 73, wherein the surface modifier is selected from the group consisting of [pharmaceutically acceptable natural surfactant is] casein, gelatin, tragacanth, [a wax, an enteric resin, paraffin,] acacia, [cholesterol, or a] and combinations thereof.

87. (New from claim 32 as first part with next claim) The process of claim [30] 73, wherein the [nonionic surfactant is] surface modifier is selected from the group consisting of a pharmaceutically acceptable polyoxyethylene fatty alcohol ether, a sorbitan fatty acid ester, a polyoxyethylene fatty acid ester, [a sorbitan ester, glycerol monostearate, a polyethylene glycol, cetyl alcohol, cetostearyl alcohol, stearyl alcohol,] a poloxamer, a polaxamine, [methylcellulose, hydroxycellulose, hydroxypropylcellulose, hydroxypropylmethylcellulose, noncrystalline cellulose, or a] and combinations thereof.

88. (New from claim 32 as second part with previous claim) The process of claim [30] 73, wherein the [nonionic surfactant is] surface modifier is selected from the group consisting of [a pharmaceutically acceptable polyoxyethylene fatty alcohol ether, a sorbitan fatty acid ester, a polyoxyethylene fatty acid ester, a sorbitan ester,] glycerol monostearate, [a polyethylene glycol,] cetyl alcohol, cetostearyl alcohol, stearyl alcohol, [a poloxamer, a polaxamine, methylcellulose, hydroxycellulose, hydroxypropylcellulose, hydroxypropylmethylcellulose, noncrystalline cellulose, or a] and combinations thereof.

89. (New from claim 33) The process of claim [30] 73, wherein the [anionic surfactant] surface modifier is selected from the group consisting of potassium laurate, triethanolamine stearate, sodium lauryl sulfate, an alkyl polyoxyethylene sulfate, sodium alginate, sodium deoxycholate, dioctyl sodium sulfosuccinate, a negatively charged glyceryl ester[s], sodium carboxymethylcellulose, calcium carboxymethylcellulose, [or a] and combinations thereof.

90. (New from claim 34) The process of claim [30] 73, wherein the [cationic surfactant] surface modifier is [a pharmaceutically acceptable quaternary ammonium compound] selected from the group consisting of benzalkonium chloride, cetyltrimethylammonium bromide, lauryldimethylbenzylammonium chloride, and [a] combinations thereof.

91. (New from claim 41) The process of claim [14 or 15] 73, wherein the surface modifier is present in an amount between 0.5% w/w and 50% w/w.

92. (New from claim 37 and 38) The process of claim [38] 73, wherein the micronized primary particles are prepared in a particle fragmentation process [is]

selected from the group consisting of sonication, milling, homogenization, microfluidization, [or] and antisolvent and solvent precipitation.

93. (New from claim 40) The process of claim [14 or 15] 73, wherein the dosage form is a tablet[, a gelatin encapsulation, or a powder].

94. (New from claim 48) A dosage form prepared by the process of claim [15] 50.

95. (New from claim 49) A dosage form prepared by the process of claim [14] 73.